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SEP 1 0 2002

510 (k) Summary

Device Name:
Normed Mini External Fixator System

Device Identification:
Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Class II

Product Code:
87 HRS (21 CFR – 888.3030)

Normed Mini External Fixator System is a unilateral (uni-bar) external fixation frame consists of a series of clamps, rods and half pins. The frame is consists of Adjustable Polyetheretherketon (PEEK) Swivel Clamps, PEEK Simple Swivel Clamps, Stainless Steel Distraction/Compression Rods, PEEK Carbon Fiber Smooth Connecting Rods and Stainless Steel Half Pins. The 4mm rods are designed to provide a connecting element for the clamps and are available in 25,40,50 and 80 mm length.

The clamps are manufactured from Polyetheretherketon (PEEK) in one size. The adjustable swivel clamp will be used with stainless steel distraction/compression rods for dynamically applying distraction or compression to the small bones of finger and toe. The simple swivel clamp will be used with Polyetheretherketon PEEK carbon fiber stabilizer rods for static fixator.

Official Contact Person:
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President
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2002

Mr. Albert Enayati
President
Osteomedics, Inc.
809 Carter Lane
Paramus, New Jersey 07652

Re: K022230
Trade/Device Name: Normed Mini External Fixator System
Regulation Number: 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulation Class: II
Product Code: HRS
Dated: June 23, 2002
Received: July 10, 2002

Dear Mr. Enayati:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for use

510 (k) Number (if known):_____

Device Name: Normed Mini External Fixator System

Indications for use:

Normed Mini External Fixator System can be used as a static fixator or dynamically applying distraction or compression to the small bones of finger and toe. The system provides treatment for small bone fractures, including severe open finger and toe fractures, highly comminuted close fractures, monunion and delayed unions (especially associated with infection), fractures associated with infections, tumor resections, figure and toe deformity corrections, burn maintenance, and bone – grafting defects and fusion of a joint. The system can be used in both adult and pediatric patients.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription use X OR OVER – THE – COUNTER USE_____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K022230

(Optional Format 1-2-96)